

K 131209

**510(k) Summary
Teratech Corporation
Terason™ uSmart3200T Ultrasound System**

MAY 24 2013

1. Sponsor:

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa,
Quality Assurance and Regulatory Affairs
Telephone: 781-270-4143

Date Prepared: March 21, 2013

2. Device Name

Proprietary Name: Terason™ uSmart3200T Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. Predicate Devices

Terason™ t3000 Ultrasound System (K112953) and Terason™ t3200 Ultrasound System (K110020)

4. Device Description

The Terason™ uSmart3200T ultrasound system is equivalent to the previously cleared version of the t3200 and t3000 Ultrasound Systems described in the following 510(k) submissions (K110020 and K112953). This system contains a proprietary ultrasound engine for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the tablet (previously laptop computer) over a FireWire (aka IEEE 1394) connection for further processing and generation and display of the ultrasound image.

The Terason™ uSmart3200T ultrasound tablet weighs 4.9 pounds (2.21 Kg) and has an 11.5" backlit touch screen. The tablet dimensions (8.82"(H) x 12.64"(W) x 1.25"(D)) are chosen to allow portability. A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning. The tablet includes a docking station (for charging) that uses a medical-grade power supply. The ultrasound transducer connector is identical to that used in the Terason™ predicate device, the t3200. Optional accessories include a cart and printer.

5. Intended Use

The Teratech Corporation Terason™ uSmart3200T is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

6. Technology Characteristics

The design and construction of the Terason™ uSmart3200T is similar to the Terason™ t3200 Ultrasound system. These systems utilize a tablet (or laptop) computer running Windows 7 to execute the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. For the uSmart3200T, the engine is housed in a compartment that is attached to the backside of the tablet computer.

The similarity and difference between the Terason™ uSmart3200T and the Terason t3200 Ultrasound System (the predicate device) include the following:

- The engines are the same with no modification in the custom beamformer chip (as compared to earlier versions of Terason ultrasound systems) that provides for improved filtering of the return signal for wider bandwidth and better resolution across the entire image field.
- The ultrasound application software has been modified to improve the user workflow and ease of use commensurate with a tablet application. The screen layout has been modified and the user controls have been changed for finger touch control to improve the efficiency for the targeted exam types.

Transducers: The Terason uSmart3200T and the BenQ UP200 will support 3 transducers. These transducers have been previously cleared.

- 12L5A: Cleared in 510k submission K112953 (February 3, 2012)
- 5C2A: Cleared in 510k submission K112953 (February 3, 2012)
- 4V2A: Cleared in 510k submission K112953 (February 3, 2012).

The following provides additional details of the three transducers, presented in this submission, that were previously cleared.

- 12L5A: equivalent indications for use, frequency settings, shape of transducer head and needle guide/software brackets. Same manufacturer, same acoustic array and patient contact materials.
- 5C2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.
- 4V2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.

B1. Non Clinical Tests

The Terason™ uSmart3200T system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety.
 - Intertek Test Record Number 100825075BOX-001.
- IEC 62366, Medical Devices: Application of usability engineering to medical devices.
 - Intertek Project: 100825075BOX-004.
- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
 - Intertek Project: 100825075BOX-003.
- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
 - IEC60601-1-2 Intertek Test Record Number, 100933162BOX-017.
- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
 - Transducer Model 5C2A: Intertek Report Number IEC60601-2-37 uSmart3200T 5C2A: 100825075BOX-006
 - Transducer Model 12L5A: Intertek Report Number IEC60601-2-37 uSmart3200T 12L5A: 100825075BOX-007
 - Transducer Model 4V2A: Intertek Report Number IEC60601-2-37 uSmart3200T 4V2A: 100825075BOX-005.
- NEMA UD 3 Acoustic Output Display
Terason uSmart3200T Ultrasound System User Guide (16-3301).
- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
 - Biocompatibility reports for all transducers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

TeraTech Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131209

Trade/Device Name: Terason™ uSmart3200T and BenQ UP200 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: May 15, 2013
Received: May 16, 2013

Dear Mr. Job:

This letter corrects our substantially equivalent letter of May 24, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Terason™ uSmart3200T and BenQ UP200 Ultrasound System, as described in your premarket notification:

Transducer Model Number

12L5A
5C2A
4V2A

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

If you have any questions regarding the content of this letter, please contact Robert Ochs, Ph.D. at (301) 796-6661.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T and BenQ UP200 Ultrasound System

Indications for Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

The Teratech Corporation Terason™ uSmart3200T (also known as the BenQ UP200) is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k)_____

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T and BenQ UP200 Ultrasound System

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal ⁿ	N	N	N		N	N	N
	Abdominal ^d :	N	N	N		N	N	N
	Intra-operative (Spec.) ^{d,e}							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric ^d :	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.) ^d :	N	N	N		N	N	N
	Neonatal Cephalic ^d :	N	N	N		N	N	N
	Adult Cephalic ^d :	N	N	N		N	N	N
	Trans-rectal ^f :							
	Trans-vaginal ^g :							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.) ^d :	N	N	N		N	N	N
	Musculo-skel. (Superfic) ^d :	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel ^d :	N	N	N		N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

^b B+M; B+PWD; B+CD; B+DPD; B+PD.

^c Harmonic Imaging (HI)

^d Includes ultrasound guidance for placement of needles, catheters.

^e Abdominal, thoracic and peripheral vessel.

^f Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Includes guidance of amniocentesis, infertility monitoring of follicle development.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
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Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T and BenQ UP200 – 5C2A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal ^h	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Abdominal ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Intra-operative (Spec.) ^{d,e}							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Small Organ (Thyroid, Breast, Testes, etc.) ^d :							
	Neonatal Cephalic ^d :							
	Adult Cephalic ^d :							
	Trans-rectal ^f :							
	Trans-vaginal ^g :							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.) ^d :	N	N	N		N	N	N
	Musculo-skel. (Superfic) ^d :	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

^b B+M; B+PWD; B+CD; B+DPD; B+PD.

^c Harmonic Imaging (HI)

^d Includes ultrasound guidance for placement of needles, catheters.

^e Abdominal, thoracic and peripheral vessel.

^f Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P¹: uses previously cleared under K112953

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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510(k)_____

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T and BenQ UP200 - 12L5A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal ^h							
	Abdominal ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Intra-operative (Spec.) ^{d,e}							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Small Organ (Thyroid, Breast, Testes, etc.) ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Neonatal Cephalic ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Adult Cephalic ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Trans-rectal ^f :							
	Trans-vaginal ^g :							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.) ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Musculo-skel. (Superfic) ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

^b B+M; B+PWD; B+CD; B+DPD; B+PD.

^c Harmonic Imaging (HI)

^d Includes ultrasound guidance for placement of needles, catheters.

^e Abdominal, thoracic and peripheral vessel.

^f Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P¹: uses previously cleared under K112953

Prescription Use x

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

510(k)

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T and BenQ UP200 - 4V2A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal ^h	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Abdominal ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Intra-operative (Spec.) ^{d,e}							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Small Organ (Thyroid, Breast, Testes, etc.) ^d :							
	Neonatal Cephalic ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Adult Cephalic ^d :	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Trans-rectal ^f :							
	Trans-vaginal ^g :							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.) ^d :							
	Musculo-skel. (Superfic) ^d :							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Cardiac Pediatric	P ¹	P ¹	P ¹		P ¹	P ¹	P ¹
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel ^d :							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

^a Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

^b B+M; B+PWD; B+CD; B+DPD; B+PD.

^c Harmonic Imaging (HI)

^d Includes ultrasound guidance for placement of needles, catheters.

^e Abdominal, thoracic and peripheral vessel.

^f Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

^g Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

^h Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P¹: uses previously cleared under K112953

Prescription Use x

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

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510(k) K131209